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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,457	04/14/2004	Chih-Ping Liu	55600-8014.US02	8343
22918	7590	10/17/2007	EXAMINER	
PERKINS COIE LLP			DANG, IAN D	
P.O. BOX 2168			ART UNIT	
MENLO PARK, CA 94026			PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/825,457	Applicant(s) LIU ET AL.	
	Examiner Ian Dang	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/06/2007, 07/24/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 07/24/2007 has been entered in full. Claims 2 and 5-11 have been cancelled and claims 1, 3, and 4 have been amended.

Claims 1, 3, and 4 are pending and under examination.

### **Information disclosure Statement**

The Examiner has considered the reference for the patent Number registration number H000,022 filed on the 1449 form on 07/24/2007.

### **Priority**

The objection to the specification is withdrawn in view of the amendment made to the specification filed on 07/24/2007.

### **Rejections Withdrawn**

#### ***35 USC § 112, Second Paragraph***

Applicant's response, arguments, amendments made to claims 1 and 4, and cancellation of claims 2 and 6, filed on 07/24/2007 have overcome the rejections of claims 1-6 under 35 U.S.C. § 112, Second paragraph. The rejections of claims 1-6 under 35 U.S.C. § 112, Second paragraph have been withdrawn.

### ***Double Patenting***

Applicant's response and terminal disclaimer filed on 07/24/2007 have overcome the

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rejections of claims 1-6 under Obviousness-Type Double Patenting. The rejections of claims 1-6 under Obviousness-Type Double Patenting rejection have been withdrawn.

### ***35 USC § 102***

Applicant's response, arguments, the declaration of Dr. Liu under 37 CFR § 1.132 (24 July 2007), and amendments made to claims 1 and 4, and cancellation of claims 2 and 6, filed on 07/24/2007 have overcome the rejections of claims 1-6 under 35 U.S.C. § 102(b). The rejections of claims 1-6 under 35 U.S.C. § 102(b) have been withdrawn.

### **Rejections Maintained**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is set forth for claims 1-6 at pages 4-6 of the previous Office action of 02 March 2007.

The rejection of claims 1, 3, and 4 is maintained. Applicant's response and arguments filed on 07/24/2007 have been fully considered but they are not persuasive.

Although Applicants have overcome the rejection under 35 USC 112, First paragraph (Written Description) regarding subject's IFN- $\gamma$  blood level relative to the IFN- $\gamma$  blood level in the absence of interferon- $\tau$ , administration, a therapeutic agent, a disease condition, and autoimmune condition, and subject's symptoms, the rejection under 35 USC 112, First paragraph (Written Description) is maintained for interferon- $\tau$ .

Applicant's arguments have been fully considered but are not found persuasive. To provide adequate written description and evidence of possession of claimed genus, the specification must provide efficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure/function correlation, and other identifying characteristics. Accordingly, in the absence of sufficient recitation of distinguishing structural/physical and identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The amendment of claim 1 does not satisfy the written description requirement because Applicant recites general characteristics regarding interferon- $\tau$  without any sufficient recitation of distinguishing structural/physical and identifying characteristics of interferon- $\tau$ . For instance, the claim recites that interferon- $\tau$  having greater than about 80% homology to ovine interferon- $\tau$ , but it does not disclose any identifying structural characteristics of these amino acids associated with the biological activity of any interferon- $\tau$ . While the specification discloses the general structural characteristics of the interferon- $\tau$  (page 7), Applicant has not provided any specific identifying structural characteristics so that one skilled in the art can correlate the interferon- $\tau$  analogs, fragments, and variants encompassed by the claims with a distinct biological function. At page 7, the specification teaches that interferon-tau, abbreviated as IFN- $\tau$  or interferon- $\tau$ , refers to any one of a family of interferon proteins having at least one characteristic

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from each of the following two groups of characteristics: (i) (a) anti-luteolytic properties, (b) anti-viral properties, (c) anti-cellular proliferation properties; and (ii) about 45 to 68% amino acid homology with  $\alpha$ -interferons and greater than 70% amino acid homology to known IFN- $\tau$  sequences (page 7, paragraph [0038]). At page 7, the specification does not provide sufficient teachings correlating the structure of the interferon- $\tau$  having greater than about 80% homology to ovine interferon- $\tau$  with its biological function, so that one skill in the art can identify the claimed interferon- $\tau$  used for treating multiple sclerosis of the instant application.

Additionally, the broad brush discussion of making and administering homologues of interferon- $\tau$  does not constitute a disclosure of a representative number of members. No such homologues were made or shown to have activity. Only the polypeptides of SEQ ID NO:2 or SEQ ID NO:3, are disclosed. The specification's general discussion of making and screening for variants constitutes an invitation to experiment by trial and error. Such does not constitute an adequate written description for the claimed homologues.

Finally, while Applicants provide information regarding the genus of the claimed polypeptide, the specification and the claims do not disclose the identifying functional characteristics of a polypeptide with at least 80% homology to ovine interferon- $\tau$ . The specification does not provide any disclosure regarding the number of amino acids changes, the identities of the amino acids and the location of these changes for the claimed interferon- $\tau$  homologue while still retaining a biological function.

***Claim Rejections - 35 USC § 112 (Enablement)***

Claims 1, 3, 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a patient with multiple sclerosis by

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reducing the blood level of IFN- $\gamma$  by administering the IFN- $\tau$  protein comprising the amino acid sequence of SEQ ID NO: 2 or 3, does not reasonably provide enablement for a method of decreasing IFN- $\gamma$  blood levels in a subject with an elevated IFN- $\gamma$  blood level due to administration of a therapeutic agent for treating multiple sclerosis comprising orally administering an IFN- $\tau$  having greater than about 80% homology to ovine interferon tau at a dosage of between  $6 \times 10^8$  -  $5 \times 10^{12}$  units to decrease the subject's IFN- $\gamma$  blood level relative to the IFN- $\gamma$  blood level in the absence of IFN- $\tau$  administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. The basis of this rejection is set forth for claims 1-6 at pages 6-11 of the previous Office action of 02 March 2007.

The rejection of claims 1, 3, and 4 is maintained. Applicant's response and arguments filed on 07/24/2007 have been fully considered but they are not persuasive.

At page 7 of the response filed 07/24/2007, Applicant argues that the claim amendments made to claims 1 and 4 and the cancellation of claims 2 and 6 have overcome the rejection under 35 U.S.C. 112, first paragraph (Enablement).

Applicant's arguments have been fully considered but are not found persuasive. The declaration under 37 CFR 1.132 filed 07/24/2007 is insufficient to overcome the rejection of claims 1, 3, and 4 based upon enablement under 35 U.S.C. 112, First paragraph as set forth in the last Office action.

Although Applicant is enabled for a method for treating a patient with multiple sclerosis by reducing the blood level of IFN- $\gamma$  by administering the IFN- $\tau$  protein comprising the amino acid sequence of SEQ ID NO: 2 or 3, Applicants do not have sufficient disclosure regarding the

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identifying characteristics or functional characteristics of the IFN- $\tau$  having greater than about 80% homology to ovine interferon tau. The teachings of IFN- $\tau$  disclose general characteristics to IFN- $\tau$ , but they do not provide any distinguishing or specific characteristics for any IFN- $\tau$  having greater than about 80% homology to ovine interferon tau. For instance, each homologue of IFN- $\tau$  results in distinct functional and structural characteristics that are required for the decrease of IFN- $\gamma$  blood levels by the administration of interferon-tau. Without sufficient disclosure in the specification, it would require undue experimentation for one of skill in the art to be able to make/use the IFN- $\tau$  variants, fragments, and analogs having greater than about 80% homology to ovine interferon tau.

Moreover, although Applicant has provided guidance regarding the polypeptide of SEQ NO:2 or SEQ ID NO:3, the specification does not teach any interferon homologues at least 80% identical to ovine interferon-tau that maintain their biological activities in order to decrease IFN- $\gamma$  blood levels.

In addition, the specification recites that that interferon-tau, abbreviated as IFN- $\tau$  or interferon- $\tau$ , refers to any one of a family of interferon proteins having at least one characteristic from each of the following two groups of characteristics: (i) (a) anti-luteolytic properties, (b) anti-viral properties, (c) anti-cellular proliferation properties; and (ii) about 45 to 68% amino acid homology with  $\alpha$ -interferons and greater than 70% amino acid homology to known IFN- $\tau$  sequences (page 7, paragraph [0038]). However, Applicant has not provided any guidance as to what amino acid residues can be added, substituted, or deleted to/from interferon-tau while retaining biological activity. The language of "an interferon tau having greater than about 80% homology to ovine interferon tau" includes a large number of peptides without any functional or identifying characteristics.



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Without sufficient disclosure in the specification, it would require undue experimentation for one of skill in the art to be able to make/use the interferon tau variants, fragments, and analogs having greater than about 80% homology to ovine interferon tau without any identifying and functional characteristics as disclosed in the claims. In addition, it would require undue experimentation to practice the invention commensurate in scope with the claims because, the claims are broadly drawn to a method of decreasing IFN- $\gamma$  blood levels in a subject with an elevated IFN- $\gamma$  blood level due to administration of a therapeutic agent for treating multiple sclerosis comprising orally administering an IFN- $\tau$  having greater than about 80% homology to ovine interferon tau at a dosage of between  $6 \times 10^8$  -  $5 \times 10^{12}$  units to decrease the subject's IFN- $\gamma$  blood level relative to the IFN- $\gamma$  blood level in the absence of IFN- $\tau$  administration. The specification's general discussion of making and orally administering all possible interferon-tau proteins constitutes an invitation to experiment by trial and error. Such experimentation is considered to be undue.

#### New Ground of Rejection

##### ***Claim Rejections - 35 USC § 112 (New Matter)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection. The amended claim represents a departure from originally filed. Although Applicant has pointed out the location for the support for the amended claims in the specification, the examiner has determined that the support is not sufficient. Claim 1 recites "orally administering an interferon-tau (IFN<sub>T</sub>) having greater than about 80% homology to ovine interferon-tau". However the definition for IFN at page 7 of the specification does not specifically teach that an interferon-tau has 80% homology to ovine IFN. The specification at page 8, paragraph [0039], discloses the definition of ovine interferon tau and states that an ovine interferon tau protein is one having about 80%, more preferably 90% homology to SEQ ID NO: 2 (page 8, paragraph [0039]).

### Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will

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be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### **Advisory Information**

Applicant is advised that the final rules on claims and continuations were published in the Federal Register Tuesday, August 21, 2007. As of November 1, 2007, the claims in each application may not exceed 5 independent claims or 25 total claims absent the applicant assisting the examination process through the filing of an Examination Support Document (ESD). The following is taken from the published rules package:

- **Applicants may present, without an ESD, up to:**
  - **Five (5) independent claims or**
  - **Twenty-five (25) total claims in an application.**
- **Applicant may present more than 5/25 claims, if applicant files an ESD before the first Office action on the merits (FAOM).**
- **The 5/25 claim threshold does not count withdrawn claims.**
  - **Applicant may provide a suggested restriction requirement (SRR) before first Office action or a restriction requirement.**
- **The 5/25 claim threshold does count all of the claims present in other copending application(s) having a patentably indistinct claim, but not the claims in issued patents.**
  - **Applicant may present up to 15/75 claims via an initial application and 2 continuation or CIP applications prosecuted serially.**

**The final rules will become effective November 1, 2007, and will apply to all pending applications as of that date.** Applicants are advised to ensure that the elected claims are compliant with the new rules to avoid delay of prosecution. There will be no change to the examiner practice prior to the date the rules become effective. Information on the new rules will be available at:

<http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>

If Applicant has any questions concerning the new rules, email [patentpractice@uspto.gov](mailto:patentpractice@uspto.gov) or call 571-272-7704.

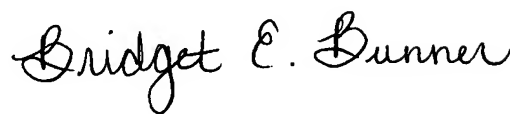
### Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
October 10, 2007



BRIDGET E. BUNNER  
PRIMARY EXAMINER